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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,339	01/25/2002	Teddy Kosoglou	CV01490K	1512

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,339	KOSOGLOU ET AL.	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-15, 32-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically an adrenergic blocker

II. Claims 1-11, 16-17, 33-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically a calcium channel blocker.

III. Claims 1-11, 18-19, 33-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically an angiotensen converting enzyme (ACE) inhibitor.

IV. Claims 1-11, 20-21, 33-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically an adrenergic stimulant.

V. Claims 1-11, 22-23, 33-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically a antihypertensive agent.

VI. Claims 1-11, 24-25, 33-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically an angiotensen II receptor antagonist.

VII. Claims 1-11, 26-27, 33-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically an anti-anginal agent.

VIII. Claims 1-11, 28-29, 33-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically a coronary vasodilator.

IX. Claims 1-11, 30-31, 33-34, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically a diuretic.

X. Claims 1-11, 33-38, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically a cholesterol biosynthesis inhibitor.

XI. Claims 1-11, 33-34, 39, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol

absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically a bile acid sequestrant.

XII. Claims 1-11, 33-34, 40, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically an AcylCoA:Cholesterol O-acyltransferase inhibitor.

XIII. Claims 1-11, 33-34, 42-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically a low density lipoprotein receptor activator.

XIV. Claims 1-11, 33-34, 41, 43-46 and 49, drawn to a pharmaceutical composition of matter for treating various cardiovascular conditions containing various sterol absorption inhibitors concomitantly with one, or more, cardiovascular agents, specifically probucol, or a derivative thereof.

XV. Claims 47-48, drawn to a method for treating vascular conditions and other related maladies by administering a pharmaceutical composition of matter containing various sterol absorption inhibitors concomitantly with one, or more cardiovascular agents.

Claims contained in Groups I-XV are directed to patentably unrelated therapeutic methods, and compositions employing a plurality of patentably distinct compound species. If Applicant selects any one of groups I-XIV for examination on the merits

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed sterol absorption inhibitor species and one cardiovascular agent species, employed to practice the claims of the invention group chosen. Additionally, Applicants are required to identify those claims directed to this therapeutic method, or composition of matter employing these single compound species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

The abovedelineated inventions differ as unrelated pharmaceutical compositions and therapeutic methods; and are independent and patentably distinct each from the other. The grouped inventions patentably distinct, a reference which would anticipate, or make obvious, the inventions of groups I-XV would not necessarily obviate or anticipate the inventions in the other group. Examiner must consider the burden posed by examining additional inventions; in view of the numerous distinct searches, and separate independent considerations, required for distinct inventions, such burden is present in the instant case. The searches are not co-inclusive as indicated by the diverse nature of the subject matter, thus, would represent an undue burden on Examiner. One skilled in the art would readily practice the invention of one of the above groups with out infringing and or practicing the invention of another group. The subject

matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

Applicant is reminded that upon the cancellation of the claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. 1.48 (b) and by the fee required under 37 C.F.R. 1.17 (h).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (571) 272-0631.

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617